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KILPATRICK TOWNSEND & STOCKTON LLP
TWO EMBARCADERO CENTER
EIGHTH FLOOR
SAN FRANCISCO, CA 94111-3834

EXAMINER	
SCHMIDTMANN, BAHAR	
ART UNIT	**PAPER NUMBER**
1623	

NOTIFICATION DATE	DELIVERY MODE
01/10/2012	ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

Docket@kilpatricktownsend.com
ipefiling@kilpatricktownsend.com
jlhice@kilpatrick.foundationip.com

Office Action Summary	Application No.	Applicant(s)	
	10/588,409	TIDMARSH, GEORGE	
	Examiner	Art Unit	
	BAHAR SCHMIDTMANN	1623	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *18 October 2011*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ An election was made by the applicant in response to a restriction requirement set forth during the interview on _____; the restriction requirement and election have been incorporated into this action.

4)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

5)☒ Claim(s) *1-20* is/are pending in the application.

5a) Of the above claim(s) _____ is/are withdrawn from consideration.

6)☐ Claim(s) _____ is/are allowed.

7)☒ Claim(s) *1-20* is/are rejected.

8)☐ Claim(s) _____ is/are objected to.

9)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

10)☐ The specification is objected to by the Examiner.

11)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

12)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *10/18/2011*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

This Office Action is in response to Applicant's Remarks filed on 18 October 2011.

Claims 1-20 are pending in the current application and are examined on the merits herein.

Information Disclosure Statement

The information disclosure statement filed 18 October 2011 fails to comply with 37 CFR 1.98(a)(3) because it does not include a concise explanation of the relevance, as it is presently understood by the individual designated in 37 CFR 1.56(c) most knowledgeable about the content of the information, of each patent listed that is not in the English language.

Specifically, item no. 12, "Notice of Reasons for Rejection from Japanese Patent Application No. 2005-552330" has not been considered because only the Japanese copy of the document has been provided without a concise explanation of its relevance.

It has been placed in the application file, but the information referred to therein has not been considered.

Maintained Rejections

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 16-20 are rejected under 35 U.S.C. 103(a) as being unpatentable over Briasoulis et al. (*European Journal of Cancer*, May 2003, vol. 39, pp.2334-2340, cited in previous Office Action) in view of Giaccone et al. (*European Journal of Cancer*, January 2004, vol. 40, pp.667-672, cited in previous Office Action).

Briasoulis et al. teaches glufosfamide can be administered using a 1-hour infusion as first-line treatment for advanced pancreatic cancer (title). Briasoulis et al. teaches patients were administered 5 g/m^2 of the glufosfamide once every three weeks (abstract; also see p. 2335, left column, last paragraph). Briasoulis et al. teaches that the glufosfamide can also be administered over a 6-hour infusion time (p.2335, right column, second paragraph). Briasoulis et al. teaches the patients treated had metastatic or inoperable (i.e. refractory) locally advanced disease (p.2335, right column, *2.2. Patient registration*). Briasoulis et al. teaches patients were treated for one to six cycles (p.2336, left column, first paragraph). Briasoulis et al. teaches gemcitabine is a known reference chemotherapeutic agent for advanced pancreatic cancer, especially in comparison to 5-fluorouracil (p.2335, left column, first paragraph). Briasoulis et al. concludes from the phase II trials that glufosfamide has modest activity against advanced/metastatic pancreatic cancer and that the response rate and duration of survival are comparable to gemcitabine (p.2339, first three paragraphs).

Briasoulis et al. does not expressly disclose administering glufosfamide to a subject in need of treatment for a chemotherapy-refractory pancreatic cancer (instant claims 16-20).

Giaccone et al. teaches administering glufosfamide by 1-hour infusion as a second-line treatment for advanced non-small cell lung cancer (title). Giaccone et al. teaches administering 5 g/m^2 by a 1-hour infusion every 3 weeks (abstract). Giaccone et al. teaches the purpose of the study was to administer glufosfamide in advanced NSCLC patients pretreated by chemotherapy (p.668, *2.1. Study design—objectives*).

It would have been obvious at the time the invention was made to administer glufosfamide to a subject having chemotherapy-refractory pancreatic cancer.

Based on the teachings of the MPEP and KSR cited in the previous Office Action, by employing the rationale in (G) Some teaching, suggestion, or motivation in the prior art that would have led one of ordinary skill to modify the prior art reference or to combine prior art reference teachings to arrive at the claimed invention; one having ordinary skill in the art would have been motivated to administer glufosfamide to a subject having chemotherapy-refractory pancreatic cancer. From Briasoulis et al., it was known at the time the invention was made that glufosfamide has efficacy against advanced metastatic pancreatic cancer. And as suggested by Giacconne et al., if advanced cancer is ineffective to known chemotherapeutics like gemcitabine, a person having ordinary skill in the art would have known to administer glufosfamide since this has been successfully demonstrated on chemotherapy-refractory cancer patients.

The skilled artisan was taught gemcitabine was known to be clinically relevant in chemotherapy-based treatment of advanced pancreatic cancer and advanced non-small cell lung cancer. The skilled artisan would have known that glufosfamide demonstrated anti-tumorous activity on similar levels as gemcitabine in treating pancreatic cancer, wherein said gemcitabine was known to be "accepted as the reference chemotherapeutic agent for advanced pancreatic cancer on the basis of its superiority with regard to clinic benefit response" (p.2335, left column, first paragraph). For that reason, glufosfamide is an art recognized equivalent to gemcitabine. Glufosfamide has been proven effective as a first-line chemotherapy agent as taught by Briasoulis et al. and a second-line chemotherapy agent for patients having chemotherapy-refractory cancer by Giaccone et al. Because of its art recognized equivalence and because it has been demonstrated to be clinically useful in multiple locally advanced cancers including phase II clinical trials against advanced pancreatic cancer, a person having ordinary skill in the art would have been motivated to administer glufosfamide to a person having chemotherapy-refractory pancreatic cancer.

Thus, the claimed invention as a whole is *prima facie* obvious over the combined teaching of the prior art.

Response to Arguments

Applicant's arguments filed 18 October 2011 have been fully considered but they are not persuasive.

I. Applicant contends Giaconne actually teaches against using glufosfamide for second-line cancer therapy.

The above argument is not found persuasive. The teaching of Giaconne must be taken in view of the prior art as a whole. According to the primary reference, Briasoulis et al., the use of gluofosfamide has proven to have modest activity against advanced/metastatic pancreatic cancer. Furthermore, Giaconne also concluded that glufosfamide administered by infusion every 3 weeks has modest activity in treating locally advanced NSCL cancer as a second-line cancer therapy (abstract). Additionally, Giaconne recognizes that glufosfamide may have advantages to ifosfamide treatment (p.671, second paragraph). It is also noted the first-line therapy utilized by Giaconne was a plantinum-based drug, and not gemcitabine. Thus, one having ordinary skill in the art may have been dissuaded from the combination of using a platinum-based drug as a first-line therapy and glufosfamide as a second-line therapy. However, since the prior art teaches other successful studies using glufosfamide therapy and since the prior art provides motivation to use gemcitabine-based therapy, one having ordinary skill in the art would *not* have been motivated to simply ignore the use of glufosfamide based combination therapy.

II. Arguments directed towards unexpected results and the data provided in table 2 is not sufficient to overcome the obviousness rejection of record for several reasons.

The data provided in table 2 (see p.6 of Remarks submitted 18 October 2011) is not commensurate in scope with the instant claims. The “unexpected results” provided

in table 2 are directed to the patient group taking a glucose lowering agent and wherein the first-line therapy was gemcitabine. All other patients, including those taking insulin had similar overall survival rates when gemcitabine was provided as a first-line therapy and best supportive care or glufosfamide was provided as a second-line therapy.

Applicant has referred to Ciuleneau et al. (*European Journal of Cancer,* 2009, vol. 45, pp.1589-1596, cited by Applicant in Information Disclosure Statement submitted 18 October 2011), as the source of the data provided in table 2. However, Applicant has not pointed to any specific passages of the Ciuleneau et al. article, nor explained how the results are commensurate in scope with the claims.

As admitted by Applicant (bottom of p.6 of Applicant's remarks, submitted 18 October 2011), although it is quite clear from the data provided in table 2, there was no statistically significant difference between patients who received glufosfamide as a second-line therapy versus patients who received Best Supportive Care as a second-line therapy. The only statistically significant data appears to be limited to a sub-group patient population having diabetes and taking some type of glucose lowering agent.

The instant claims are currently directed towards administering glufosfamide as a second-line therapy to a patient having received any type of chemotherapeutic drug as a first-line therapy. Thus, the patient population of the instant claims is not commensurate in scope with the data provided in table 2 of Applicant's remarks and Ciuleneau et al.

Evidence as to unexpected benefits must be" clear and convincing" *In re Lohr*, 137 USPQ 548 (CCPA 1963). Applicant has the burden to explain the experimental

evidence. See *In re Borkowski and Van Venrooy* 184 USPQ 29 (CCPA 1974). Submission of the data found in table 2 should also include names of the glucose lowering agents - and identification of where support can be found for these agents in the instant specification.

The rejection is hereby **maintained**.

Claims 1-15 are rejected under 35 U.S.C. 103(a) as being unpatentable over Noble et al. (*Drugs*, 1997, vol. 54, no. 3, pp.447-472, cited in previous Office Action) in view of Briasoulis et al. (cited above) and Kozuch et al. (*The Oncologist*, 2001, vol. 6, pp.488-495, cited in previous Office Action) and in further view of Giaconne et al. (cited above).

Noble et al. teaches gemcitabine was effective in treating patients having advanced pancreatic cancer that were surgery or radiotherapy-refractory pancreatic cancer patients (p.460, *3.2 Pancreatic Cancer*). Noble et al. teaches other dosage regiments of gemcitabine include 1000 mg/m^2 once a week for seven weeks, followed by a one week rest (seven week *dosage* cycle) and then once a week for three weeks with a one week rest (four week cycle), (p.461, table VII). Noble et al. teaches that gemcitabine should be administered in 30 minute infusions (p.465, last paragraph). Noble et al. teaches combined therapy with gemcitabine and fluorouracil has been used in patients with advanced pancreatic cancer (p.469, second paragraph). Noble et al. suggests that this combination and others involving gemcitabine and other chemotherapeutic agents should be explored in the future (p.469, second paragraph).

Noble et al. teaches chemotherapy regiments directed at treating non-small lung cancer comprising administering gemcitabine combinations with ifosfamide, wherein the gemcitabine was administered by infusion at 1000 mg/m^2 once weekly for 3 of 4 weeks and ifosfamide was administered by infusion at 1500 mg/m^2 on days 8 to 12 of a 28 day cycle (p.457, last paragraph). Noble et al. teaches this combination resulted in an objective response rate of 22% for NSLC (p.457, last paragraph).

Noble et al. does not expressly disclose administering a combination of *glu*fosfamide with gemcitabine (instant claims 1-15). Noble et al. does not expressly disclose the order of administration (instant claims 8, 9 and 13-15).

Briasoulis et al. teaches as discussed above.

Kozuch et al. teaches the efficacy of doublet combinations of gemcitabine, ironotecan, cisplatin and 5-fluorouracil have been successful in patients having advanced pancreatic cancer (p.489, left column, second paragraph). Kozuch et al. teaches gemcitabine was the first drug approved for the treatment of pancreatic cancer and has a favorable toxicity profile (p.491, last paragraph). Kozuch et al. teaches gemcitabine-based doublets with 5-fluorouracil, cisplatin and irinotecan are feasible and the data suggests consistent improved response rates, response duration, overall survival and quality of life compared with gemcitabine alone (p.492, first paragraph). Kozuch et al. teaches gemcitabine-based combination therapy involves administering gemcitabine on the same day as the other chemotherapeutic drugs (p.490, first paragraph).

Giaccone et al. teaches as discussed above.

It would have been obvious at the time the invention was made to administer a combination of gemcitabine and glufosfamide to a patient having advanced pancreatic cancer.

Based on the teachings of the MPEP and KSR cited in the previous Office Action, by employing the rationale in (G) Some teaching, suggestion, or motivation in the prior art that would have led one of ordinary skill to modify the prior art reference or to combine prior art reference teachings to arrive at the claimed invention; one having ordinary skill in the art would have been motivated to administer a combination of gemcitabine and glufosfamide to a patient having advanced pancreatic cancer.

A person having ordinary skill in the art would have known at the time the invention was made from all of the cited references, that gemcitabine is a leading chemotherapeutic agent used in the treatment of locally advanced pancreatic and non-small cell lung cancer. Noble explicitly teaches gemcitabine combination therapy is useful against non-small cell lung cancer, and explored as a means for treating advanced pancreatic cancer. This reference encouraged those of ordinary skill in the art to explore gemcitabine combinations with known and novel chemotherapeutic agents. It should be noted that one of the combinations mentioned includes gemcitabine with ifosfamide, wherein glufosfamide as instantly claimed is simply a beta-glucose derivative of ifosfamide. The skilled artisan would have known from Noble that this specific combination did in fact provide some success in the treatment of non-small cell lung cancer, a locally advanced cancer.

Kozuch et al. actually demonstrates what Noble suggested, that gemcitabine chemotherapeutic combinations can be useful in treating advanced pancreatic cancer. From Briasoulis and Giaccone et al., respectively, the skilled artisan would have known at the time the invention was made that glufosfamide, a derivative of ifosfamide can be effective in treating advanced pancreatic cancer and non-small cell lung cancer. Briasoulis et al. goes on to teach that glufosfamide can be useful as a first-line chemotherapeutic agent and Giaccone et al. teaches that glufosfamide can also be useful as a second-line chemotherapeutic agent.

As discussed above, the prior art recognizes both gemcitabine and glufosfamide as art equivalents in the treatment of advanced pancreatic cancer. The art also strongly suggests and teaches gemcitabine-based combinations. More notably, Noble teaches a combination of gemcitabine with ifosfamide, wherein glufosfamide is a beta-glucose derivative of ifosfamide. Both gemcitabine and glufosfamide have been successfully used to treat advanced pancreatic cancer. Thus in view of their common therapeutic utility, a suggestion in the prior art to administer gemcitabine-based combinations and in view of the success in treating locally advanced cancer by administering gemcitabine with ifosfamide, one having ordinary skill in the art would have been motivated to administer a combination of both gemcitabine and glufosfamide to a person having locally advanced cancer and more specifically to a person having advanced pancreatic cancer.

From Kozuch et al., the skilled artisan would have known at the time the invention was made that gemcitabine can be administered sequentially on the same day

as other known chemotherapeutic agents in combination-based therapy. Additionally, a person having ordinary skill in the art would have known that both gemcitabine and glufosfamide are art recognized equivalents and would have been motivated to administer both drugs on the same day to provide maximum effect in killing the tumorous cells. Because it was known to sequentially administer gemcitabine with other chemotherapeutics, it would have been obvious to administer the gemcitabine before or after the glufosfamide infusion.

Combination of the two drugs would also necessarily require optimization of dosage frequency and is well within the level of ordinary skill in the art. For example, the prior art teaches administering glufosfamide at 5 g/m^2, which is broadly and reasonably considered about 4.5 g/m^2, over an infusion period of 1-hour every three weeks. However, it is also known that gemcitabine administration can be given in four week cycles wherein the drug is actively infused for the first three weeks followed by a resting week. Therefore, it would have been obvious to modify the administration of glufosfamide in a gemcitabine based combination-based therapy such that it is also provided once every four weeks instead of every three weeks.

Additionally, from Briasoulis et al., one having ordinary skill in the art would have known that glufosfamide can be administered by infusion over 1 to 6-hours. Therefore, it would have been obvious to administer the glufosfamide over 4 hours.

Thus, the claimed invention as a whole is *prima facie* obvious over the combined teaching of the prior art.

Response to Arguments

Applicant's arguments filed 18 October 2011 have been fully considered but they are not persuasive.

I. Applicant contends one having ordinary skill in the art would not have known which of the four drugs (gemcitabine, ironotecan, cisplatin and 5-fluorouracil) taught by Kozuch could be substituted without decreasing the effect of the combination as a whole. Applicant contends the Office Action does not adequately explain why one having ordinary skill in the art would have been motivated to select just one drug, i.e. gemcitabine, leave out the other three, but then substitute a second drug (glufosfamide) which the other three references teach should be used as a monotherapy.

The above arguments are not found persuasive. The instant claims recite the transitional phrase “comprising”, which allows for additional elements or method steps to be performed. One having ordinary skill in the art need only been motivated to administer gemcitabine in combination with glufosfamide. From the primary reference, Noble et al., the ordinary artisan would have expressly known that gemcitabine combination therapy with fluorouracil to treat advanced pancreatic cancer has already been known. Thus, in light of Noble and Kozuch, the skilled artisan would have known that a combination of two chemotherapeutic drugs or four chemotherapeutic drugs can be used to treat cancer. Furthermore, the three drugs gemicitabine, fluorouracil and glufosfamide have been used to treat pancreatic cancer wherein the three drugs have similar pharmacological activity. Therefore, the skilled artisan would have been

motivated to substitute the fluorouracil for glufosfamide in either the Noble or Kozuch reference, or simply combine gemcitabine with glufosfamide.

II. Second, Applicant noted that the ordinary artisan would have expected a different tissue distribution of glufosfamide versus ifosfamide due to the presence of the glucose in the glufosfamide molecule, and because of the distribution of cell-surface glucose receptors.

It is unclear what Applicant's arguments are in this regard. Is Applicant arguing that because of the distribution of cell-surface glucose receptors that one having ordinary skill in the art would or would not have expected clinical efficacy with glufosfamide? The use of carbohydrates, i.e. glucose, to delivery target molecules to the tissue is a well-known technique in the art precisely because of the presence of cell-surface glucose receptors. Briasoulis et al. expressly teaches that pancreatic carcinoma is accompanied by an overexpression of glucose transporters (p.2335, second paragraph). Briasoulis et al. teaches the active alkylating moiety isophosphoramide (ifosfamide) attached to the β-D-glucose gives it the potential to exploit the transmembrane transport system of glucose (p.2335, second paragraph). And Briasoulis et al. teaches that glufosfamide is directed into tumor cells by SAAT1, a low-affinity sodium-dependent β-D-glucose co-transporter, while other glucose transporters may also play a role in the intracellular translocation of the glufosfamide (p.2335, second paragraph). Therefore, the skilled artisan would actually have expected greater efficacy with the glufosfamide over the ifosfamide.

III. Arguments directed towards unexpected results and the data provided in table 1 is not sufficient to overcome the obviousness rejection of record.

First, the prior art recognizes that the combination of gemcitabine with ifosfamide resulted in an objective response rate of 22% in treating locally advanced cancer. Although the data was directed towards treating non-small cell lung cancer, treatments directed towards locally advanced pancreatic are similar to treating locally advanced non-small cell lung cancer. Furthermore, gemcitabine combination therapy has been used to treat both advanced pancreatic cancer and NSCL cancer. Thus, one having ordinary skill in the art would have had a reasonable expectation of similar synergistic effects in treating advanced pancreatic cancer.

Second, as discussed above, one having ordinary skill in the art would have had a reasonable expectation of success in using glufosfamide over ifosfamide precisely because of the glucose moiety which allows the active alkylating ifosfamide compound to be delivered across glucose transport membranes and into tumorous cells.

Thus, the results (18% response rate with the combination of gemcitabine and glufosfamide) do not appear to be unexpected in light of the prior art teaching a 22% response rate with the combination of gemcitabine and ifosfamide.

Thus, the rejection is hereby **maintained**.

Conclusion

In view of the rejections to the pending claims set forth above, no claim is allowed.

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to BAHAR SCHMIDTMANN whose telephone number is (571)270-1326. The examiner can normally be reached on Mon-Fri 9am-5pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Shaojia Jiang can be reached on 571-272-0627. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/SHAOJIA ANNA JIANG/
Supervisory Patent Examiner, Art Unit 1623

/BAHAR SCHMIDTMANN/
Patent Examiner
Art Unit 1623